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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,380	01/27/1999	MATITYAHU FRIDKIN	FRIDKIN=1	3626

7590 07/08/2002

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EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 07/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/117,380

Applicant(s)

FRIDKIN ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Prosecution Application

The request filed on 1/22/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/117,380 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants cancellation of claim 1, amendment of claims 2-9, 12 and 13, addition of new claims 14, 15, and 16-24 in Paper No. 25, 4/30/2002, is acknowledged. Claims 2-9 and 12-24 are still pending.

Applicants' arguments filed on 4/30/2002, Paper No. 25, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 15 (16-24 dependent on) are indefinite in that the recitation "... (C) a peptide obtained by elongation of (A) or (B) at the N- and/or C-terminal, but not

including an entire protein;..." is unclear. It is unclear as to applicants intent in the limitation "but not including an entire protein", specifically what does applicant consider to be an "entire protein" and at what point does a "peptide" become an "entire protein"?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Barr et al. (U.S. Patent No: 4,732,973, issued 3/22/1998).

The rejection is stated in the previous office action as it applied to previous claims 1-4 and 9. Applicants cancelled claim 1, and amended claims 2-4 and 9, to depend from new claim 14.

As previously discussed, Barr et al. teach a proteinaceous composition to inhibit naturally occurring serine proteases, particularly an amino acid sequence analogous to human α 1-antitrypsin, which is modified at the active site while maintaining protease inhibition. Barr et al. specifically claim an analog of human alpha-1-antitrypsin wherein the amino acid corresponding to the methionine at position 358 is changed to a valine. This variant comprises the sequence "...leu₃₅₃-glu-ala-ile-pro-val-ser-ile₃₆₀..." which anticipates claims 15-18 and 22. Further, Barr et al. teaches that this variant inhibits

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human elastase activity (See columns 13-15) and that polypeptide fragments comprising said "leu₃₅₃-glu-ala-ile-pro-val-ser-ile₃₆₀" sequence may be used.

Applicants traverse this rejection as it applies to claim 15 on the basis that applicants preferred peptides are those in which His₉₅ is substituted by Phe. Applicants further submit that Barr only covers Thr at position 95, and accordingly new claim 15 has been submitted which leaves the whole range of possibilities for position 94, but the possibilities for position 95 do not include Thr, thus applicants submit that claim 15 is not anticipated by Barr et al. This argument is not found persuasive because it is pointed out to applicants that Barr et al. teaches the sequence "...leu₃₅₃-glu-ala-ile-pro-val-ser-ile₃₆₀..." which anticipates such a sequence with a **Ser** at the corresponding position 95, not a **Thr** as applicants submit. Thus claims 15-18 and 22 are anticipated by Barr et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barr et al. (U.S. Patent No: 4,732,973, issued 3/22/1998).

As discussed above, Barr et al. teach a proteinaceous composition to inhibit naturally occurring serine proteases comprising an analog of human alpha-1-antitrypsin wherein the variant comprises the sequence "...leu₃₅₃-glu-ala-ile-pro-val-ser-ile₃₆₀..." Further, Barr et al. teaches that this variant inhibits human elastase activity (See columns 13-15) and that failure to inhibit elastase in the lungs can result in pulmonary emphysema or acute respiratory distress syndrome. Barr et al. further teach the use of said proteinaceous compositions for a number of therapeutic purposes. One of ordinary skill in the art would be motivated to create a pharmaceutical composition comprising a variant of human alpha-1-antitrypsin wherein the variant comprises the sequence "...leu₃₅₃-glu-ala-ile-pro-val-ser-ile₃₆₀..." as taught by Barr et al. and using such a pharmaceutical composition as an anti-inflammatory medication and a means of protecting a host from elastase related damage to the lungs associated with pulmonary emphysema or acute respiratory distress syndrome. The reasonable expectation of success comes from the results of Barr et al. and the high degree of knowledge in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', with a long horizontal stroke extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
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July 5, 2002